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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,406	03/17/2004	Thomas Weisel	SUS1.PAU.02	5563

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EXAMINER
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SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/803,406

Applicant(s)

WEISEL ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11,12 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,10,13,15-17 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 18-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The abstract of the disclosure is objected to because of undue length. An abstract must be a concise description of the novelty of the invention made within 50 to 150 words. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 recites the limitation of a sharp needle when claim 1 already recites a sharp needle. Applicant does not have support for a device with two sharp needles thus claiming new matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10, 13 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Toy et al (US Patent 5,618,290).

Toy et al disclose a device (**1, Figures 2-12**) comprising: a hollow elongate shaft (**11**); a handle assembly (**16**) coupled to the shaft (**11**); a thumb slide (**17**) moveable on the handle housing in a proximal and distal position relative to the needle assembly creating a free suture state when distal and a captured/locked state when proximal; an actuating rod (**3, Figure 4**) having a proximal end and distal end; a needle assembly (**6, 7, 8, 9**) disposed at the distal end of rod (**3**) movable back and forth with the actuating rod between an extended and retracted state; the needle assembly having integral (clearly shown where **3** points in **Figure 4**) cylindrical bifurcated portions (backing arm **9** and gathering arm **7**) defining a suture slot between; the arms (**7, 9**) are separate due to spring forces in the extended state and proximate/contacting due to shaft (**11**) in the retracted state; the needle assembly also comprising a sharp distal tip (**6**) integral with arm (**7**). In regard to claims 5-7, it is noted that there are "portions" of each arm that meet the criteria as broadly claimed. In regard to claims 22-24, **Figures 6-12** clearly demonstrate the method as claimed.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu (US Patent 6,936,054).

Chu discloses (**Figures 1A-2I**) a surgical device extending along an axis and having a proximal end and a distal end, the device being operable to move a suture

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through body tissue, comprising: an elongate shaft having a hollow configuration (**104**); a handle assembly coupled to the shaft (**102**); an actuating rod (**110**) having a proximal end and a distal end, the actuating rod being disposed to extend between the handle assembly and the shaft; a needle assembly disposed at the distal end of the actuating rod (**124**) and movable with the actuating rod between an extended state and a retracted state (**Figures 2A and 2D**); bifurcated portions (**126 and 128**) of the needle assembly defining a suture slot between, the bifurcated portions having a proximate relationship when the needle assembly is in the retracted state and having a separated relationship when the actuating rod is in the extended state (**Figure 2B**); the needle assembly being biased to the retracted state; and the bifurcated portions being biased to the separated relationship.

Claims 13 and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Diduch et al (US Patent Application Publication 2002/0147456).

Diduch discloses a method for placing suture across a body wall of a patient, comprising the steps of: providing a suture device including a hollow shaft (**20**) with a proximal end and a distal end, an actuating rod disposed in the shaft (**2**), and a needle assembly (**10**) carried by the rod between a deployed position (**Figure 2b**) and a retracted position (**Figure 2a**); providing the needle assembly with a needle having a sharp distal tip; bifurcating the needle to form at least one pair of arms defining a suture slot (**6**), the arms being movable between a proximate position associated with a first slot size (**Figure 2a**) and a spaced position associated with a second slot size greater than the first slot size; (**Figure 2b**) penetrating the body wall with a needle assembly in

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the retracted position and the arms in the proximate position; and advancing the needle assembly to the deployed position to move the arms to the spaced position associated with the second slot size; forming a channel in one of the arms to provide for side-loading of the suture into the suture slot; wherein the slot has a proximal end and a distal end and the forming step includes the step of forming the channel in proximity to the distal end of the slot (**Paragraphs 0054-0058**).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 15-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skiba et al (US Patent 6,723,107).

Skiba et al disclose a surgical suturing device (**Figures 18-21**) comprising: a needle assembly (**Figures 20 and 21**) having a needle (**2002**) movable in a needle housing (rest of **Figure 20**) between a free suture state (**Figure 20**) and a locked suture state (**Figures 21**); a captured state exists inbetween the two extremes; the needle housing constitutes one bifurcated portion as well as having a sharp tip integrally formed on its distal end; the needle constitutes the second bifurcated portion having a proximate relationship to the first portion when in the captured and locked suture state; the needle and needle housing are integral in regard to being assembled into one working device; a handle assembly (**1802**) including a longitudinal handle housing sized

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and configured to releasably receive the needle assembly (**1808/Figures 20/21**); a thumb slide (**1804**) assembly releasably coupled to the needle and movable longitudinally on the handle housing between a distal position and a proximal position; the proximal position of the thumb slide assembly being associated with the needle in the free suture state; and the distal position of the thumb slide assembly being associated with the needle in the captured suture state; a needle lock included in the thumb slide assembly and having a releasable locking relationship with the needle (**Column 4, Line 44 through Column 5, Line 20**).

Skiba et al fail to disclose where the thumb slide is operated such that in the distal position is associated with the free suture state, the proximal position is associated with the captured suture state, and that a ratchet mechanism is used to lock the relationship of the needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the manner the thumb slide operated since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167. It would have been further obvious to use a ratchet mechanism to perform the locking relationship disclosed in **Column 4, Line 44 through Column 5, Line 20** because it is well known in the art that a ratchet mechanism provides for good holding, quick adjustment, and ease of manufacture.

### ***Response to Arguments***

Applicant's arguments filed on August 8<sup>th</sup>, 2006 have been fully considered but they are not persuasive.

In regard to Toy et al, applicant asserts that Toy et al does not disclose a sharp needle tip **integral** with a bifurcated portion. Dictionary.com Unabridged v 1.0.1 defines integral as: *consisting or composed of parts that together constitute a whole*. Clearly, the tip and bifurcated portions together form a structure together. It does not matter whether they are molded as one, welded together, screwed together, glued together, hinged, etc. They would even be “integral” if one would not function without the other.

In regard to Skiba et al, applicant's amendments necessitated a 35 U.S.C. 103(a) analysis thus making the arguments moot in regard to 35 U.S.C. 102(e).

In regard to Chu, applicant's amendments necessitated a new interpretation of Chu, which should clearly demonstrate that flap (128) is one bifurcated portion pivotally connected to the second bifurcated portion (126). They are biased apart and closed from members (132 and 134).

In regard to Diduch et al, applicant argues that Diduch et al does not disclose a free suture state. Diduch et al allows a “free suture state” by not applying any frictional force to a suture. As the slot closes, it'll first restrict (captured state) movement of the string through and then after additional force lock (locked state) the string relative to the device. As for the step of “bifurcating the needle” it is clearly evident from the drawings that the step is clearly performed. The bifurcated end is more open outside distal of the tube than proximal/inside. So when pushing the needle out of the shaft, the needle bifurcates to freely allow a suture to pass through the slot formed between the bifurcated portions.



***Allowable Subject Matter***

Claims 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
October 23<sup>rd</sup>, 2006



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER